UNIVERSITY OF MANCHESTER NATIONAL PRIMARY CARE RESEARCH AND DEVELOPMENT CENTRE AND UNIVERSITY OF YORK HEALTH ECONOMICS CONSORTIUM (NICE EXTERNAL CONTRACTOR)

Health economic report on piloted indicator(s)

QOF indicator area: Peripheral arterial disease (aspirin, anti-platelet therapy)

Potential output: Recommendations for NICE Menu

Contents

Introduction 2
Piloted indicator 2
Economic rationale for the indicator 2
Objective 2
Type of health economic analysis 2
Delivery cost of indicator 2
Clinical-effectiveness of indicator 2
Eligible population 3
Baseline level of achievement 3
Potential cost-savings to the NHS 3
Population 3
QOF Payments 4
QOF Points 4
Thresholds 4
Results 4
Discussion 5
References 6
Appendix A: Threshold Analysis 7
Appendix B: Background to cost-effectiveness evidence (QOF) 9

Introduction

This briefing paper is intended to provide a summary of the economic evidence generated on the proposed 'Pilot two' Peripheral Arterial Disease (PAD) indicator. The format of this paper is intended to provide the QOF Advisory Committee with sufficient information upon which to make a recommendation on whether the indicator is economically justifiable.

Piloted indicator

NM33: The percentage of patients with peripheral arterial disease with a record in the preceding 15 months that aspirin or an alternative anti-platelet is being taken (unless a contraindication or side-effects are recorded)

Economic rationale for the indicator

Patients with PAD are at increased risk of major cardiovascular events even when adjusting for other cardiovascular risk factors that have significant implications on patients' quality and quantity of life and the consumption of NHS healthcare resources. The SIGN guideline for the diagnosis and management of peripheral arterial disease states "antiplatelet therapy is recommended for patients with symptomatic peripheral arterial disease" [1].

Objective

To evaluate whether the proposed indicator represents a cost effective use of NHS resources.

Type of health economic analysis

A threshold analysis approach is applied. Insufficient evidence is available on the health benefits of treating PAD patients with aspirin or an alternative anti-platelet therapy, measured by quality-adjusted life years (QALYs).

Delivery cost of indicator

In the base case analysis, the delivery cost of the indicator included one practice nurse visit and an annual supply of aspirin (75mg daily dose). Aspirin therapy was the most widely studied antiplatelet drug [2]. One nurse visit is costed at £12 [3] and a year's supply aspirin at £12.12 [4], providing a total delivery cost of £21.72.

If drug therapy is to be prescribed by a general practitioner, the total delivery cost of the indicator will be estimated at £45.72.

Clinical-effectiveness of indicator

In a systematic review conducted by the Antithrombotic Trialists' Collaboration patients with PAD experienced a 23% reduction in serious vascular events when treated with anti-platelet therapy [2]. Non-fatal myocardial infarction, non-fatal stroke or vascular deaths were classified as a serious vascular event.

Eligible population

During the pilot phase, the eligible population at 21 piloted practices ranged between 0.91% - 0.92% of the total practice population. In the base case analysis, the eligible practice population for this indicator was assumed to be 0.92%.

Baseline level of achievement

Pre-pilot the median practice achievement recorded at 21 sites was estimated to be 77.4% and 78.7% at the post-pilot phase reported by 13 primary care sites. In the base case a baseline level of achievement of 77.4% is assumed.

Table 1: Achievement of the proposed indicator reported by the pilot sites

PAD 3 indicator	Median (50th centile)	5th centile	75th centile
Pre-pilot	77.4	53.5	81.6
Post-pilot	78.7	57.8	82.6

Potential cost-savings to the NHS

Based on an estimated prevalence of 0.92%, the PAD population in England who are eligible for anti-platelet therapy is approximately 476,668.

Published evidence suggests that the 5-year rate of major cardiovascular events in symptomatic PAD is approximately 25% [5]; this was converted into a yearly rate. Assuming 77.4% of the PAD population are currently prescribed aspirin therapy, there are approximately 23,833 serious vascular events per annum. If 0% of PAD patients received aspirin therapy it is estimated that 29,344 events would occur per annum. In the base case, a weighted cost of myocardial infarctions and strokes was taken from the NHS Reference Costs (2009/10), and estimated to be £1,785 per event [6]. The estimated cost of serious vascular events per PAD patient per annum treated with and without antiplatelet therapy is estimated to be £84.63 and £109.91 respectively.

The potential cost savings to the NHS from reducing serious vascular events is estimated at £25.28 per PAD patient per annum.

In the sensitivity analysis we will consider varying the cost to the NHS of a serious vascular event. In previous NICE costing reports [7], the cost of per serious vascular event ranged between £3,015 and £8,589.

Population

In the base case, the threshold analysis of the proposed indicator was conducted based on the total practice population registered with practices in England, that is, 8,228 practices with a mean practice size of 6,297 [8].

Table 2: Practice information for all UK members

Country	Number of practices	Number of patients

England	8,228	6,297
Scotland	1,014	5,122
Wales	488	6,146
Northern Ireland	357	5,011

QOF Payments

Each QOF point is assumed to result in a payment of £130.51. This is the forecast value per point in England during 2011/12 (source; Information Centre).

Table 3: Value per point for all UK members (most recently available)

Country	**Value per point**
England	£130.51
Scotland	£127.29
Wales	£130.47
Northern Ireland	£122.00

QOF Points

The economic analysis considers the cost-effectiveness of incentivising the proposed activity over a range of QOF points. The range of QOF points evaluated were agreed by NICE, YHEC and the economic sub-group to justify the practice successfully completing the activity.

In the base case analysis, 7 points were allocated to the proposed PAD indicator. Sensitivity analysis will be followed out between the agreed lower and upper bounds of 4 and 12 points (i.e. the range evaluated).

Thresholds

The minimum threshold is set to 40% and the incentivised payments increase linearly up to the maximum threshold of 90%. This is based on indicators of similar nature currently in the national QOF (AF 03, CHD 09, and STROKE 12).

Results

The cost savings achieved through reducing serious vascular events in the PAD population are greater than the delivery cost of the indicator. However, as we introduce additional costs to the NHS through the QOF payments, the benefits are substantially reduced in the base case analysis.

The threshold analysis suggests the indicator is not economically justifiable when considering the cost savings absorbed within the NHS, even at the lower bound of four QOF points. This is largely due to the high level of baseline achievement which demonstrates that larger increases in practice achievement are required to make the indicator economically justifiable from this perspective.

Sensitivity analysis demonstrated that the cost per serious vascular event was highly significant to the recommendations of this analysis. When the lower bound of £3,015 per serious vascular event as reported in the NICE clinical guideline 67 costing report is applied [7], the indicator remained cost ineffective. When the upper bound of £8,589 was applied per serious vascular event the indicator was deemed value for money up to potentially 10 QOF points when large increases in achievement were achieved. The potential cost savings to the NHS from reducing serious vascular events in these two scenarios were estimated to be £42.69 and £121.61 per PAD patient per annum respectively.

The analysis is insensitive to changes in delivery cost. A scenario where the delivery cost was set to only the prescribed treatment was investigated in line with delivery cost estimate provided by the NICE costing team however the conclusions of the paper remained unchanged.

Discussion

It is important to emphasise this is a restricted analysis and caution is needed in its interpretation. The conclusions from the threshold analysis only focus the potential savings absorbed within the system (i.e. NHS) that will be required to justify incentivising the indicator. This analysis does not quantify, in monetary terms, the value of any potential survival gains or reduced morbidity from treating PAD patients with statin therapy which substantially restricts the analysis. Although it is likely there will be health benefits from treating PAD patients with statin therapy, the base case analysis can be viewed as conservative.

There is an absence of evidence reported on health outcomes measured by quality adjusted life years (QALYs) in the PAD population receiving anti-platelet therapies. Without this information it is difficult to make a recommendation on the likely QALYs gained through incentivising the indicator.

There is evidence to suggest that anti-platelet have health-related quality of life benefits in other populations where clinical-effectiveness has been demonstrated, e.g. non-valvular atrial fibrillation population [9]. In this economic evaluation it estimated patients over 65 years of age could gain an additional 0.78 QALYs over their lifetime when treated with aspirin compared with no treatment (discounted at 3%). If it is reasonable to assume a similar QALY gain (health benefit) can be achieved in the PAD population, the indicator would be economically justifiable at the upper bound of the analysis, i.e. 12 QOF points.

Appendix B suggests even if the lifetime QALY gain in the PAD population from statin therapy was reduced by 50% (i.e. 0.39 QALYs) the indicator is likely to be highly cost effective at the upper bound of QOF payments. It is likely that the lifetime costs of treating PAD patients with statin therapy would increase the incremental cost of the indicator considered in this analysis due to a potential increase in survival. This would imply a health gain of larger than 0.034 QALYs would be required to justify 12 QOF points, as presented in Appendix B.

References

[1] Diagnosis and management of peripheral arterial disease; A national clinical guideline (89). Scottish Intercollegiate Guidelines Network. October 2006.

[2] Antithrombotic Trialists' Collaboration (2002). Collaborative meta-analysis of randomised trials of antiplatelet therapy for prevention of death, myocardial infarction, and stroke in high risk patients. BMJ; **324**, 71-86.

[3] Unit Costs of Health & Social Care 2010. Personal Social Services Research Unit (PSSRU). Complied by Lesley Curtis. University of Kent.

[4] British National Formulary 61.

[5] Hackam DG, Sultan NM, Criqui MH (2009). Vascular protection in peripheral artery disease: systematic review and modelling study. Heart; **95**: 1098-1102.

[6] NHS Reference Costs 2009/10. Department of Health. Published: 17 February 2010.

[7] Lipid modification. Costing report; Implementing NICE guidance. NICE clinical guideline 67. May 2008.

[8] General Practice Trends in the UK. NHS Information Centre. Published: 22 March 2011.

[9] Eckman MH, Falk RH, Pauker SG (1998). Cost-effectiveness of Therapies for Patients With Nonvalvular Atrial Fibrillation. Arch Intern Med; **158**: 1669-1677.

Appendix A: Threshold Analysis

Pilot two indicator - PAD 3 pharmacological management: Threshold Analysis

Value per point achieved	£130.51
Number of practices	8,228
Mean practice population	6,297

Minimum threshold	40%
Maximum threshold	90%

Basline achievement

Eligible population (mean % of practice population)	0.92%
Baseline achievement (mean % of eligible patients)	77.4%

Cost-effectiveness estimates

Incremental cost (£ per patient)	£21.72

Points	2	3	4	5	6	7	8	9	10	11	12

National totals

Expected Achievement	QOF payments (£000s)											Change in treatment cost (£)
25%	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£5,425,090
30%	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£4,907,428
35%	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£4,389,767
40%	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£3,872,106
45%	£215	£322	£430	£537	£644	£752	£859	£966	£1,074	£1,181	£1,289	-£3,354,445
50%	£430	£644	£859	£1,074	£1,289	£1,503	£1,718	£1,933	£2,148	£2,362	£2,577	-£2,836,783
55%	£644	£966	£1,289	£1,611	£1,933	£2,255	£2,577	£2,899	£3,222	£3,544	£3,866	-£2,319,122
60%	£859	£1,289	£1,718	£2,148	£2,577	£3,007	£3,436	£3,866	£4,295	£4,725	£5,154	-£1,801,461
65%	£1,074	£1,611	£2,148	£2,685	£3,222	£3,758	£4,295	£4,832	£5,369	£5,906	£6,443	-£1,283,800
70%	£1,289	£1,933	£2,577	£3,222	£3,866	£4,510	£5,154	£5,799	£6,443	£7,087	£7,732	-£766,139
75%	£1,503	£2,255	£3,007	£3,758	£4,510	£5,262	£6,013	£6,765	£7,517	£8,269	£9,020	-£248,477
80%	£1,718	£2,577	£3,436	£4,295	£5,154	£6,013	£6,873	£7,732	£8,591	£9,450	£10,309	£269,184
85%	£1,933	£2,899	£3,866	£4,832	£5,799	£6,765	£7,732	£8,698	£9,665	£10,631	£11,597	£786,845
90%	£2,148	£3,222	£4,295	£5,369	£6,443	£7,517	£8,591	£9,665	£10,738	£11,812	£12,886	£1,304,506
95%	£2,148	£3,222	£4,295	£5,369	£6,443	£7,517	£8,591	£9,665	£10,738	£11,812	£12,886	£1,822,167
100%	£2,148	£3,222	£4,295	£5,369	£6,443	£7,517	£8,591	£9,665	£10,738	£11,812	£12,886	£2,339,829

Minimum cost savings per patient required to be deemed cost-effective

25%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
30%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
35%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
40%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
45%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
50%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
55%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
60%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
65%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
70%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
75%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
80%	£160	£230	£299	£368	£438	£507	£576	£646	£715	£784	£854
85%	£75	£102	£128	£155	£182	£208	£235	£262	£288	£315	£342
90%	£57	£75	£93	£111	£129	£147	£165	£183	£201	£218	£236
95%	£47	£60	£73	£86	£99	£111	£124	£137	£150	£163	£175
100%	£42	£52	£62	£72	£82	£91	£101	£111	£121	£131	£141

Pilot two indicator - PAD 3 pharmacological management: Threshold Analysis

Value per point achieved	£130.51		Societal value of a QALY	£25,000	
Number of practices	8,228				
Mean practice population	6,297				
		Basline achievement			**Cost-effectiveness estimates**
Minimum threshold	40%	Eligible population (mean % of practice population)	0.92%		Incremental cost (£ per patient)	£21.72
Maximum threshold	90%	Baseline achievement (mean % of eligible patients)	77%		

Points	0	3	4	5	6	7	8	9	10	11	12

National totals

Expected Achievement	**QOF payments (£000s)**											**Change in treatment cost (£)**
25%	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£5,425,090
30%	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£4,907,428
35%	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£4,389,767
40%	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£3,872,106
45%	£0	£322	£430	£537	£644	£752	£859	£966	£1,074	£1,181	£1,289	-£3,354,445
50%	£0	£644	£859	£1,074	£1,289	£1,503	£1,718	£1,933	£2,148	£2,362	£2,577	-£2,836,783
55%	£0	£966	£1,289	£1,611	£1,933	£2,255	£2,577	£2,899	£3,222	£3,544	£3,866	-£2,319,122
60%	£0	£1,289	£1,718	£2,148	£2,577	£3,007	£3,436	£3,866	£4,295	£4,725	£5,154	-£1,801,461
65%	£0	£1,611	£2,148	£2,685	£3,222	£3,758	£4,295	£4,832	£5,369	£5,906	£6,443	-£1,283,800
70%	£0	£1,933	£2,577	£3,222	£3,866	£4,510	£5,154	£5,799	£6,443	£7,087	£7,732	-£766,139
75%	£0	£2,255	£3,007	£3,758	£4,510	£5,262	£6,013	£6,765	£7,517	£8,269	£9,020	-£248,477
80%	£0	£2,577	£3,436	£4,295	£5,154	£6,013	£6,873	£7,732	£8,591	£9,450	£10,309	£269,184
85%	£0	£2,899	£3,866	£4,832	£5,799	£6,765	£7,732	£8,698	£9,665	£10,631	£11,597	£786,845
90%	£0	£3,222	£4,295	£5,369	£6,443	£7,517	£8,591	£9,665	£10,738	£11,812	£12,886	£1,304,506
95%	£0	£3,222	£4,295	£5,369	£6,443	£7,517	£8,591	£9,665	£10,738	£11,812	£12,886	£1,822,167
100%	£0	£3,222	£4,295	£5,369	£6,443	£7,517	£8,591	£9,665	£10,738	£11,812	£12,886	£2,339,829

QALYs gained per patient required to be deemed cost effective

25%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
30%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
35%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
40%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
45%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
50%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
55%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
60%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
65%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
70%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
75%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
80%	0.001	0.009	0.012	0.015	0.018	0.020	0.023	0.026	0.029	0.031	0.034
85%	0.001	0.004	0.005	0.006	0.007	0.008	0.009	0.010	0.012	0.013	0.014
90%	0.001	0.003	0.004	0.004	0.005	0.006	0.007	0.007	0.008	0.009	0.009
95%	0.001	0.002	0.003	0.003	0.004	0.004	0.005	0.005	0.006	0.007	0.007
100%	0.001	0.002	0.002	0.003	0.003	0.004	0.004	0.004	0.005	0.005	0.006

Appendix B: Background to cost-effectiveness evidence (QOF)

This appendix provides background information to the approach used for evaluating the economic implications of existing and potential new indicators for the QOF. The approach has been developed by economists at the Universities of York and East Anglia, and presented previously to the QOF Advisory Committee.

The approach to cost effectiveness considers two issues:

1. Is the activity/intervention described by the indicator cost effective?
2. What level of payment is economically justifiable to increase the activity?

The first question seeks to determine whether an activity or intervention will result in benefits which are greater than the costs of undertaking the activity. In this analysis, health benefits are assumed to be measured in Quality Adjusted Life Years (QALYs) which can be valued in monetary terms at £25,000 each. The net benefit calculation subtracts the delivery costs and the QOF payments from the monetarised health benefits

Net benefit = (monetised benefit – delivery cost) – QOF payment

The second question relates to the level of QOF payments which can be justified to increase levels of desired activities whilst retaining net benefits to the NHS. This is directly relevant to negotiations relating to the implementation of indicators and decisions on the number of QOF points to be allocated to a particular indicator. Where sufficient data are available, detailed sensitivity analysis on QOF points and uptake levels can be undertaken within the cost-effectiveness model. This paper provides information on the cost-effectiveness of the pilot indicators, to inform the decisions of the QOF Advisory Committee.

Nature of cost-effectiveness evidence

A couple of conditions must hold for an indicator to be deemed cost-effective:

1. The intervention/activity itself must be cost-effective. In the UK, NICE use an implicit threshold of £20,000 to £30,000 per QALY gained.
2. The intervention/activity must lead to an increase in the number of eligible patients receiving the intervention/activity.

The main challenge associated with cost-effectiveness analyses of the indicators is the availability of data on the costs and health benefits of implementing the targeted activities. The main source of this has been the review of NICE clinical guidelines and published literature. For several indicators there is the additional problem of linking them directly to changes in patient outcomes so that net health benefits can be assessed.

Many of the indicators relate to areas of clinical management which have been shown to be cost-effective if correctly carried out. However, the indicators themselves do not always measure the delivery of treatment; they frequently require the assessment and documentation of a patient's disease status, or whether they have had a particular diagnostic test. These types of indicators may lead to changes

in treatment and improvement in patient outcomes, but it is not certain to happen. In reviewing the piloted indicators we have applied a three-way classification:

i. Indicators which relate directly to a change in treatment;

ii. Indicators which change the availability of information available to the treating clinician in a disease where there is a proven therapy;

iii. Indicators which change the availability of information but which do not directly inform a treatment decision.

Indicators in category (i) are most amenable to cost-effectiveness analysis as they can lead directly to a change in outcome. Those in category (ii) may also lead to a change in outcomes if the new information is acted upon. To carry out the cost-effectiveness an assumption must be made on the likelihood of such a change in management taking place. The third category is least amenable to cost-effectiveness analysis as improvement in the process of information collection is unlikely to change the patient outcome.

The main challenge associated with the analyses outlined above, is the availability of evidence on the costs and health benefits of existing and new clinical indicators. Two economic approaches have been derived:

Approach one – Net benefit analysis

A net benefit approach has been recommended as the most appropriate means of evaluating whether an indicator can be considered cost effective. Cost effectiveness is intended to consider whether the costs associated with an indicator are outweighed by the benefits accrued by the health service. When a robust evidence base is available for an indicator, they can be identified as a category (i) indicator. When an indicative evidence base is available for category (ii) indicators it is possible to apply the net benefit approach.

Approach two – Threshold analysis

Threshold analysis has been identified as the approach when considering indicators with a thin evidence base, i.e. missing data. For example, where the costs of delivering an indicator are known or can be easily estimated, but the effectiveness is unknown, then it is possible to identify the minimum level of effectiveness necessary for an indicator to be considered cost effective, in terms of quality-adjusted life years (QALYs) per patient per annum. This can also be expressed in terms of a minimum cost-saving (£) per patient per annum. This approach is applied to the category (ii) indicators with a thin evidence base.

Data on costs of implementation can be estimated from descriptions of the actions required to meet the potential indicator targets. The nature and extent of any QOF payment is unknown at this stage. Judgement can be made on the potential cost-effectiveness of an indicator if the difference between the costs and benefits of implementation is known. If this is relatively small, then there will be little scope for incentive payments if positive net benefits are to be achieved.

Piloted indicators are reviewed to determine which are associated with a therapeutic benefit that can be measured in QALY terms. Indicators which do not have a direct link to therapeutic benefit (process indicators) are subject to a preliminary economic

appraisal. The danger of attributing a therapeutic benefit to a process indicator is that the necessary assumptions may be seen, in some cases, as tenuous.

Although the cost-effectiveness of indicators that do not have a direct link to therapeutic benefit may be unclear, this does not mean that they are poor value for money, but rather that new studies are required to produce the data needed to determine their cost-effectiveness (Walker *et al*. 2010).

References

Walker S, Mason AR, Claxton K, Cookson R et al. (2010) Value for money and the Quality and Outcomes Framework in primary care in the UK NHS. British Journal of General Practice; May 2010, e213-220.